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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/121,017    07/22/98    IMAMURA    T    382.1019

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EXAMINER

SAUNDERS, D

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

10/03/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No. 121,017	Applicant(s) IMAMURA et al
Examiner D. SAUNDERS	Group Art Unit 1044

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 12/2/99
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-15 is/are pending in the application.
- ☐ Of the above claim(s) 7-13, 15 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-3, 5-6, 14 is/are rejected.
- ☒ Claim(s) 4 is/are objected to.
- ☒ Claim(s) 1-15 are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_
- ☒ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

Art Unit: 1644

Claims 1-15 are pending.

Applicant's election without traverse of Group I (claims 1-16 and 14) in Paper No. 21 is acknowledged.

The drawings are objected to because various figures contain Japanese characters. Various figures have more than one subfigure, each of which must be separately designated --e.g. Figure 5 as Figures 5A and 5B. Correction is required.

The disclosure is objected to because of the following informalities: The Brief Description of the Drawings must refer to each subfigure designated in any corrected drawings -- e.g. reference must be made to Figures 5A and 5B. Any subsequent references to the figures in the Examples must refer to the particular subfigure(s) that are relevant.

Appropriate correction is required.

Claim 14 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

Claims 3,6 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 3 "its allied factor" is unclear. Applicant's disclosure has not indicated what degree of homology would indicate that such factors are "allied".

Art Unit: 1644

6/5/01  
The term "greatly" in claim <sup>6</sup>~~10~~ is a relative term which renders the claim indefinite. The term "greatly" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The disclosure gives no guidance as to how much change in tertiary structure would be considered "great". Thus the notes and bounds of the claimed invention are unclear.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the proteins having the SEQ ID NOS recited in part (a), does not reasonably provide enablement for the deletions, substitutions, additions or modifications of these SEQ ID NOS recited in part (b). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Applicant's disclosure has given inadequate direction as to what amino acid residue of these polypeptides are critical for their FGF activity. Therefore applicant is inviting one to conduct an undue amount of experimentation in order to find out which of these residues can be deleted, substituted, added or modified without destroying FGF activity.

Furthermore applicant has given no direction as to what kinds of "modifications" of amino acid residue side chains may be made without destroying the activity of FGF.

9/6/01  
Claims 1-3, <sup>5-6</sup>~~6~~ and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Senoo et al (5,360,896).

Art Unit: 1644

Senoo et al teach muteins of FGF in which a glycosylation site has been added. The glycosylated FGFs have improved properties such as increased stability, prolonged blood clearance time, and improved activity. See col. 12, lines 21 +. Since activity is retained or improved it is considered inherent that the muteins of Senoo et al have been "functionalized" as instantly claimed, when one interprets this term as defined at instant specification page 7.

Claim 2 is rejected since the muteins of Senoo et al would have N-linked sugar chains. See col. 5, lines 1-34.

Claim 6 is included in the rejection, because, inherently, the tertiary structure of the protein cannot be greatly changed if activity is retained in the muteins.

Claim 5 is considered anticipated because the recited SEQ ID NOS include a sequence derived from human acidic FGF. Senoo et al teach acidic FGF (col. 3, line 26) as a protein from which muteins with added glycosylation site (s) may be obtained. The examiner notes that the sequences recited in claim 5 include only a portion of the acidic FGF sequence and a portion of a protein with glycosylation sites (e.g. ryudocan). However, part (b) of claim 5 is sufficiently broad as to the number of deletions, substitutions and insertions that may be provided in the recited SEQ ID NOS that it is proper to consider these as encompassing a mutein of acidic FGF taught by Senoo et al. For example, the ryudocan sequence could be deleted, and the left out portion of acidic FGF would be added, and the glycosylation sites could be inserted with the result that the sequence would be within the scope of claim 5 part (b).

claim  
5(b)  
rejected

Art Unit: 1644

Claim 4 has limitations not taught a suggested by Senoo et al, who do not teach providing sugar chains bonded to a peptide which in turn is bonded to the FGF. For this reason claim 5, part (a) is considered not taught by Senoo et al

Any inquiry concerning this communication should be directed to D. Saunders at telephone number (703) -308-3976.

Saunders/LR

September 15, 2000

*David A. Saunders*  
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PRIMARY EXAMINER  
ART UNIT ~~182~~ 1644